REMARKS

Claims 1-3 and 5-12 were examined. No claims are added, amended or canceled. Claims 1-3 and 5-12 remain in the Application.

The Patent Office rejects claims 1-2 and 5-12 under 35 U.S.C. §103(a). Reconsideration of the pending claims is respectfully requested in view of the following remarks.

A. 35 U.S.C. §103(a): Rejection of Claims 1-3 & 5-10

The Patent Office rejects claims 1-3 and 5-10 under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,162,202 of Sicurelli, et al., (Sicurelli) in view of U.S. Patent No. 5,746,713 of Hood, et al. (Hood). Sicurelli discloses a flexible irrigation syringe tip for irrigating and delivering medication to intra-tooth canals during endodontic route canal treatment. *See* column 4, lines 15-18.

> As shown in FIG. 4 flexible syringe needle 10c of syringe 1c may have dispensing ports as lateral side ports dispensing fluid substantially transverse to a longitudinal axis of flexible syringe needle 10c, or a plurality of longitudinally extending, spaced apart lateral side ports 17c, wherein the plurality of lateral side ports 17c extend between the fluid discharge end 15c and connecting end 12c.

Column 4, lines 51-57.

With respect to Figure 9, Sicurelli discloses that a flexible syringe needle may be connected to remote pump 200 for directing fluid at a controlled rate to a tooth canal. See column 5, lines 28-31. The pump may have a pressure control to increase pressure to allow flow through smaller gauge needles and for safely avoiding excess pressure. See column 5, lines 41-43. Finally, the flexible syringe needle may have a pressure control means 500 communicating with pressure sensor 550 for controlling the flow of the fluid discharged from the flexible needle. See column 5, lines 48-51.

Sicurelli describes its device for use in endodontic procedures and particularly designed to be used for intra-canal irrigation of the interior of a tooth canal. Sicurelli notes that its device "may also be used to introduce fluids or medicine into body cavities such as a vascular blood

vessel or vessels during vascular surgery, or into foramina holes in bones during surgery, or to negotiate within body cavities around rigid surfaces of bones or artificial steel plates during orthopedic surgery." Col. 3, lines 48-54.

Hood describes a phacoemulsification needle for fragmenting eye tissue at a surgical site. The needle includes an elongated distal end with one or more outlets 36 for dispensing fluid. "Phacoemulsification involves the fragmentation of lens tissue and is performed, for example, in cataract surgery." Col. 1, lines 8-10. Hood describes "needle 12 for cutting and/or fragmenting eye tissue (not shown) at a surgical site by radiating ultrasonic energy into the eye tissue." Col. 3, lines 27-30.

Independent claim 1 describes a system including a needle comprising a body capable of penetrating tissue with an opening and at least one aperture located at a predetermined distance from the opening. The system also includes a fluid measurement assembly coupled with a portion of the needle to measure pressure of a fluid dispensed in the needle. The pressure measurement assembly is configured to measure (1) a first pressure that is the pressure of the fluid as the fluid is dispensed through the needle at a constant rate; (2) a second pressure that is a pressure change when the needle contacts the tissue and the first opening becomes occluded; and (3) a third pressure that is a second pressure change when the needle penetrates the tissue and the aperture becomes occluded.

To rely on a reference under 35 U.S.C. §103(a), it must be analogous prior art. The reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned. MPEP 2141.01(a).

Claim 1 is directed to a system for detecting tissue contact by a needle and needle penetration depth into tissue. See Application, paragraph [0002]. Such a system finds beneficial use in delivering (e.g., injecting) fluid (e.g., drug) into a tissue penetrated by the needle.

Sicurelli describes an environment where its needle device is placed in a tooth canal. Sicurelli does not describe a needle device that involves penetrating tissue or penetrating it sufficiently to occlude a laterally placed aperture on its flexible needle. The tooth canal has already been formed. Sicurelli penetrates an open canal, not a tooth.

Sicurelli describes an embodiment of a flexible needle including a plurality of lateral dispensing ports 17C (Figure 4) and 17D (Figure 5). If the flexible needle could penetrate tissue (which Applicant does not concede), such an embodiment would not be suitable in an environment where the needle was required to dispense fluid into tissue since presumably the lateral dispensing ports would be blocked. Sicurelli apparently recognizes this limitation as it identifies alternative uses as introducing "fluids or medicines into body cavities, such as a vascular blood vessel or vessels." Col. 3, lines 48-51 (emphasis added). Dispensing a fluid or medicine from a needle with lateral dispensing ports in a "cavity" such as a lumen of a blood vessel is quite different from dispensing through the same ports in tissue. In the former case, the lateral dispensing ports may not be obstructed while in the latter case, the dispensing ports could very well be.

Hood also does not describe a system or device for penetrating tissue. Hood describes a phacoemulsification device that could be used, for example, to remove a cataract. Such a needle does not penetrate eye tissue per se. Instead, eye tissue is cut or fragmented and the tip of the phacoemulsification needle is maneuvered around the fragmented tissue to break it up. The tip of the needle is used to scrape fragmented tissue on the eye rather than penetrate it.

In addition to each of Sicurelli and Hood being non-analogous art, there is nothing in Sicurelli and Hood to suggest the desirability, and thus obviousness, of making the combination. See MPEP 2143.01 and In re Fulton, 73 USPQ2d 1141 (Fed. Cir. 2004). Sicurelli is directed to a needle device that may be placed in a tooth canal. Sicurelli describes other possible cavities as well, but one of those cavities is not the eye. Hood describes it device only in reference to procedures on the eye and does not describe penetrating any cavity to deliver fluid. Therefore, one looking to possibly modify Sicurelli for use in any of its disclosed cavities would not look to the teachings of Hood or vice versa. Sicurelli also describes a flexible needle presumably so the needle can bend within a canal. See col. 4, lines 41-43 ("if flexible needle 10a is straight, it bends while encountering a curved tooth canal within a tooth"). This would not be feasible if the phacoemulsification needle of Hood were substituted nor would it be feasible to replace the needle of Hood with the flexible needle of Sicurelli for cutting and/or fragmenting eye tissue.

For the above-state reasons, claim 1 is not obvious over the combined teachings of Sicurelli and Hood. Claims 2-3 and 5-10 depend from claim 1 and therefore contain all the

limitations of that claim. For at least the reasons stated with respect to claim 1, claims 2-3 and 5-10 are not obvious over the cited references.

Applicant respectfully requests that the Patent Office withdraw the rejection to claims 1-10 under 35 U.S.C. §103(a).

B. 35 U.S.C. §103(a): Rejection of Claims 11-12

The Patent Office rejects claims 11-12 under 35 U.S.C. §103(a) as obvious over Sicurelli in view of Hood and further in view of U.S. Patent No. 6, 546,787 of Schiller, et al. (Schiller). Schiller is cited for teaching a computer processor and feedback system to be used in connection with needle systems.

Claims 11-12 depend from claim 1 and therefore contain all the limitations of that claim. As noted above with respect to claim 1, Sicurelli and Hood are non-analogous art and there is no motivation to combine Sicurelli and Hood. The computer processor and visual feedback system of Schiller does not cure the defects of the Sicurelli and Hood combination. Accordingly, claims 11-12 are not obvious over the combination of references.

Applicant respectfully requests that the Patent Office withdraw the rejection of claims 11-12 under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,
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I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

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